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*Admitted only in Maryland *Admitted only in Virginia •Practice Limited to Federal Agencies

December 3, 2003

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Art Unit 1642

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 10/040,945; Filed: January 9, 2002

For: Modular Assembly of Antibody Genes, Antibodies Prepared Thereby

and Use

Inventor:

BETTER et al.

Our Ref:

0610.005000I/MAC

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. First Supplemental Information Disclosure Statement;
- 2. A listing of the cited documents (AL1- AM7 and AR1-AS55) on form PTO-1449 (55 pages); and
- 3. Return Postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox PLLC.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skgf.com

Commissioner for Patents December 3, 2003 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Michaela A. Cimbala

Michele A. Cimbala Attorney for Applicant Registration No. 33,851

MAC/krc

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re application of:

Robinson et al.

Appl. No. 10/040,945

Filed: January 9, 2002

For: Modular Assembly of Antibody

Genes, Antibodies Prepared

Thereby and Use

Confirmation No. 5282

Art Unit:

1642

Examiner:

To be assigned

Atty. Docket: 0610.005000I/MAC

First Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of these documents were filed in the parent application, US Application No. 09/722,315, filed on November 28, 2000.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

The Examiners's attention is directed to co-pending U.S. Patent Application No. 09/722,425, filed November 28, 2000, which is directed to related technical subject matter. The identification of the U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language documents, Document Nos. AL3, AN3, AN5, AO5, and AO6 cited on Form PTO-1449.

Document No. AL3, Patent No. JP 60-155132, is in the Japanese language. This document relates to immunoglobulin production by recombinant host cells. An English language abstract is provided as Document No. AT53.

Document No. AN3, Patent No. JP 61-47500, is in the Japanese language. This document relates to chimeric antibodies and the production thereof. An English language abstract is provided as Document No. AR54.

Document No. AN5, Patent No. JP 62-502586, is in the Japanese language. This document relates to the construction of hybrid genes. An English language abstract is provided as Document No. AS54.

Document No. AO5, Patent No. JP 63-068087, is in the Japanese language. This document relates to a DNA and amino acid sequence that contributes to the expression of pectic acid lyase. An English language abstract is provided as Document No. AT54.

Document No. AO6, Patent No. EP 0 324 162, is in the German language. This document relates to the production of antibodies in bacteria. An English language abstract is provided as Document No. AT55.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

Robinson et al. Appl. No. 10/040,945

- 3 -

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This First Supplemental Information Disclosure Statement is being filed within three months of the date of filing of a national application. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Michele A. Cimbala

Attorney for Applicants

miles A. Cirles

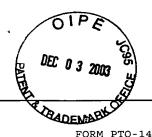
Registration No. 33,851

Date: Duc. 3, 2003

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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	AL1	EP	0 048 970 A2	04/07/1982	Europe				Yes No	
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	AN1		0 088 994 B1	 	Europe				Yes No	
	A01	WO	83/03971	11/24/1983	WIPO				Yes	
	AP1	EP	0 102 634 A1	03/14/1984	Europe				Yes	
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,	AR	1	medium of H	Escherichia co	Secretion of heterologii," <i>Nucl. Acids Res</i> (August 1986).					
	AS	1	partial ger	Alexander, A. et al., "Y heavy chain disease in man: cDNA sequence supports partial gene deletion model," <i>Proc. Natl. Acad. Sci.</i> USA 79:3260-3264, National Academy of Science of the USA, Washington, D.C. (1982).						
	AT	1	a bacterial	Amster, O. <i>et al.</i> , "Synthesis of part of a mouse immunoglobulin in light chain : a bacterial clone," <i>Nucl. Acids Res.</i> 8:2055-2065, Oxford University Press. Oxford, England (1980).						
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FORM PTO-1449
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ATTY. DOCKET NO. 0610.0050001	APPLICATION NO. 10/040,945
APPLICANT ROBINSON et al.	
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	AL2	EP	0 120 694 A	2 10/03/1984	Europe				Yes No
	AM2	GB	2 137 631 A	10/10/1984	Great Britain				Yes No
	AN2	EP	0 125 023 A	11/14/1984	Europe				Yes No
	A02	EP	0 126 338 A	11/28/1984	Europe				Yes No
	AP2	EP	0 133 321 A	02/20/1985	Europe				Yes No
			OTHER (Incl	uding Author,	Title, Date, Pertiner	nt Pages,	etc.)		
	AR	<u>2</u>	DNA encodi	Anand, N.N. et al., "Synthesis and expression in Escherichia coli of cistronic DNA encoding an antibody fragment specific for Salmonella serotype B O-antigen, Gene 100:39-44, Elsevier Science Publishers B.V., Amsterdam, Netherlands (June					
	AS	2	Fv Genes E Biol. Chem	Anand, N.N. et al., "Bacterial Expression and Secretion of Various Single-chain Fv Genes Encoding Proteins Specific for a Salmonella Serotype B O-Antigen," J. Biol. Chem. 266(32):21874-21879, American Society for Biochemistry and Molecular Biology, Inc., Baltimore, MD (November 1991).					
	AT	2	Possible C k12," Acta Publishers	Axelsson, K., "Bacterial Lipopolysaccharides and Glutathione Mixed Disulfides as Possible Contaminants of Human Growth Hormone Produced with the Use of E. coli k12," Acta Chemica Scandanavica Series B 39:69-71, Munksgaard International Publishers, Copenhagen, Denmark (1985), Communication at the Meeting of the Swedish Biochemical Society in Stockholm Sweden, August 42-25th, 1984.					
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	AM3	EP	0 154 539 A2	09/11/1985	5	Europe				Yes No
	AN3	JP (61-47500	03/07/1986	6	Japan				Yes X No
	A03	EP (0 171 496 A3	02/19/1986	6	Europe				Yes No
	AP3	EP (0 173 494 A3	03/05/1986	6	Europe				Yes No
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	AS	3	surfaces: Th	Barbas III, C.F. et al., "Assembly of combinatorial antibody libraries on phage surfaces: The gene III site," <i>Proc. Natl. Acad. Sci.</i> USA 88(18):7978-7982, National Academy of Sciences of the USA, Washington, D.C. (September 1991).						7982,
	AT	<u>3</u>	Myeloma Cell	Bebbington, C.R. et al., "High-Level Expression of A Recombinant Antibody From Myeloma Cells Using A Glutamine Synthetase Gene As An Amplifiable Selectable Marker," <i>Bio/Technol</i> . 10:169-175, Nature Publishing Co., New York (February 1992).						.ectable
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	AL4	WO :	86/01533	03/13/1986	WIPO				Yes No
	AM4	EP	0 184 187 A2	06/11/1986	Europe				Yes No
	AN4	EP	0 194 276 B1	09/17/1986	Europe				Yes No
	A04		86/05513	09/25/1986	WIPO				Yes
	AP4	WO	86/05812	10/09/1986	WIPO				Yes No
		1	OTHER (Inclu	ding Author,	Title, Date, Pertinent	Pages,	etc.)		
	AR	<u>4</u>	Beckwith, C Curr. Topic 1986).	J. and S.Ferross Microbiol.	o-Novick, "Genetic Studi Immunol. 125:5-27, Spri	les on i	Protei elag,	n Export Berlin, G	in Bacteria," Germany (July
	AS	<u>4</u>	Beggs, J.D. <i>Benzon Sym</i> p	., "Multiple-o	copy Yeast Plasmid Vecto , Munksgaard, Copenhag e	ors," <i>M</i> en, Den	ol. Ge mark (net. Yeas 1981).	st, Alfred

Bernstein, K.E., et al., "Nucleotide Sequence of a Rabbit IgG Heavy Chain from the Recombinant F-I Haplotype," *Immunogenet*. 18(4):387-397, Springer-Verlag, Berlin, Germany (1983).

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	AM5	EP	0 234 592 A1	09/02/1987	Europe				Yes No	
	AN5	JP	62-502586	10/08/1987	Japan				Yes X No	
	A05	JP	63-68087	03/26/1988	Japan				Yes X No	
	AP5	EP	0 266 663	05/11/1988	Europe				Yes No	
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	AR	<u>5</u>	Fragment,"	Science 240:	nerichia coli Secre 1041-1043, American C. (May 1988).					
	AS	<u>5</u>	Fragments i	etter, M. and A.H. Horwitz, "Expression of Engineered Antibodies and Antibod ragments in Microorganisms," <i>Meth. Enzymol</i> . 178:476-496, Academic Press Inc ew York, NY (November 1989).						
	АТ	<u>5</u>	Bacteria," and the Imm	tter, M. et al., "Production And Scale Up of Chimeric Fab Fragments From cteria," Advances in Gene Technology: The Molecular Biology of Immune Disd the Immune Response, <i>Proc. Of the 1990 Miami Bio/Technol. Winter Symp</i> .:105. IRL Press. New York (July 1990).					une Diseases	

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APPLICATION NO. 10/040,945

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	AN1						Ye N		
	A01						Ye N		
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	AS	<u>7</u> Role of th	Briggs, M.S. and L.M. Gierasch, "Molecular Mechanisms of Protein Secretion: The Role of the Signal Sequence," <i>Adv. Prot. Chem.</i> 38:109-180, Academic Press, Inc., San Diego, CA (January 1986).						
	AT	7 lymphocyte USA 82:556	Brown, N.A. et al., "Immunoglobulin J_H , C_μ , and C_Y gene rearrangements in human B lymphocytes clonally transformed by Epstein-Barr virus," <i>Proc. Natl. Acad. Sci. USA</i> 82:556-560, National Academy of Sciences of the USA, Washington, D.C. (January 1985).						
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	AS	8	cells," P	Calos, M.P. et al., "High mutation frequency in DNA transfected into mammalian cells," <i>Proc. Natl. Acad. Sci. USA</i> 80:3015-3019, National Academy of Sciences of the USA, Washington, D.C. (May 1983).						
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FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 0610.0050001	APPLICATION NO. 10/040,945
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	AS	14		Ghrayeb, J., et al., "Secretion Cloning Vectors in Escherichia coli," EMBO J. 3:2437-2442, IRL Press Limited, Oxford, England (October 1984).					
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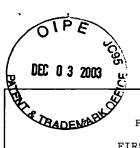
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FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 0610.0050001	APPLICATION NO. 10/040,945
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